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COMMENTS:

DOES NOT CONTAIN CBI



AkzoNobel

Tomorrow's Answers Today

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January 24, 2013

US EPA Office of Pollution Prevention and Toxics
EPA East Building Room 6428
Attn: Section 8(e)
1201 Constitution Avenue, NW
Washington, DC 20004



Cc: Polymer Chemicals bv
Arkema France
Pergan GmbH
United Initiators GmbH & Co. KG

SUBJECT: TSCA 8(e) Notice



Dear TSCA Section 8(e) Coordinator:

On behalf of Akzo Nobel Polymer Chemicals LLC we are submitting results on a 14-day range-finder for an OECD 422 Combined Repeat Dose Toxicity with Reproduction/Developmental Toxicity Screening Test, with tert-butyl peroxyvalate CAS# 927-07-1.

The test item was administered orally (by gavage) to Hsd.Brl.Han: Wistar rats (n=5 animals/sex/dose) once a day at 0 (vehicle control), 50, 250 and 750 mg/kg bw/day for 14 days.

Clinical Observations

750 mg/kg bw/day:

Decreased activity (5/5), palpebral closure (3/5), piloerection (3/5), hunched back (2/5), prone position (1/5) and salivation (5/5) were observed in male animals. Slight, moderate or marked salivation and decreased activity were present for several days (from day 1 and 7 up to the end of study, respectively), while palpebral closure, piloerection, hunched back and prone position appeared on the last three days of the study.

Slight or moderate salivation (5/5) and slight activity decrease (5/5) were noted for female animals from days 1 and 7, respectively.

Hematology

In the male animals, statistical significances were noted for the higher value of neutrophil granulocytes (NEU), slightly lower mean percentages of lymphocytes (LYM), eosinophil granulocytes (EOS) and reticulocytes (RET) at 750 mg/kg bw/day.

In the female animals, the values of red blood cell count, hemoglobin concentration (HGB), hematocrit value (HCT) and mean corpuscular hemoglobin content (MCH) were slightly but significantly reduced and platelet count (PLT) was elevated at 750 mg/kg bw/day.

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Clinical Chemistry

750 mg/kg bw/day:

Significant increase of alanine aminotransferase (ALT), aspartate aminotransferase (AST), and decrease of total protein concentration were detected in male animals with severe clinical signs, body weight decrease.

Statistically significant differences with respect to controls were noted for higher mean concentration of potassium (K⁺) and albumin–globulin ratio (A/G), lower concentration of chloride (Cl⁻), albumin (ALB) and total protein (TPROT).

In female animals, activity of alanine aminotransferase, concentration of cholesterol (CHOL), bile acids (BAC), calcium (Ca²⁺) and potassium (K⁺) were higher than in the control group. The concentration of total bilirubin, creatinine, glucose (GLUC) and A/G ratio were lower than the control value.

250 mg/kg bw/day:

In the male animals, the mean concentrations of chloride and total protein were below and the potassium concentration was above the appropriate control value.

Necropsy

750 mg/kg bw/day:

Pale kidneys (1/5 male), smaller than normal thymus (4/5 male), seminal vesicles (4/5 male) and prostate (1/5 male), and hyperemic mesenteric lymph nodes (1/5 male and 1/5 female) were observed.

250 mg/kg bw/day:

Pale kidneys were noted in 1/5 males.

Organ Weights

The absolute organ weights and organ weights relative to the body weight were not considered to be relevant for evaluation because of the significantly lower mean body weight (- 20 % with respect to controls) of male animals administered with 750 mg/kg bw/day.

750 mg/kg bw/day:

In the male animals, the body weight, thymus and prostate weights relative to brain weight were significantly lower and the adrenal weight relative to the brain weight was higher than the control value.

In the female animals, liver weights (absolute and relative to body and brain weights), kidney and spleen weights (both relative to body weight) exceeded the values of control group. The weights of thymus (absolute and relative to body and to brain weights) and absolute ovaries weight were less with respect to controls.

250 mg/kg bw/day:

In the male animals, liver and kidney weights relative to body weights were higher with respect to controls. The liver weights relative to body and brain weights were above the control in female animals.

Please contact me at (312) 544-7061 if you have any questions regarding this letter.



AkzoNobel
Tomorrow's Answers Today

Sincerely,

Louette Rausch
Expertise Leader Regulatory Affairs Americas
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From: (312) 544-7005
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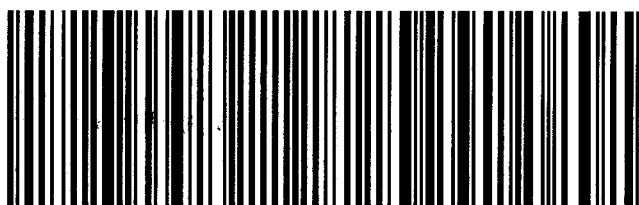
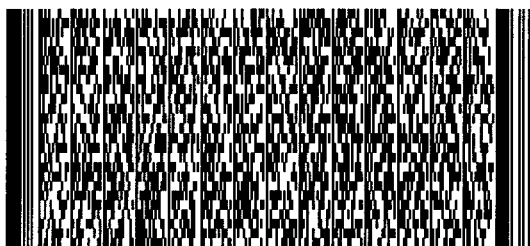
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